AF ZW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	: 09/308,223
Applicant	: Georg KALLMEYER et al.
Filed	: August 12, 1999
Title:	: STABLE LYOPHILIZED PHARMACEUTICAL SUBSTANCES FROM MONOCLONAL OR POLYCLONAL ANTIBODIES
TC/A.U.	: 1642
Examiner	: Brandon J. Fetterolf
Docket No.	: 2924-139
Customer No.	: 6449
Confirmation No.	: 5876

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

December 21, 2006

APPELLANT'S REPLY BRIEF UNDER 37 C.F.R. §41.41

Sir:

The following comprises the Applicant's Reply to the examiner's answer dated October 31, 2006 and remailed on November 29, 2006. This Reply Brief is being timely filed.

STATUS OF CLAIMS

Claims 13, 15-18 and 22-36 are pending in the application. Claims 13, 15-18 and 22-36 were rejected in the Final Office Action dated November 1, 2005. Claims 1-12, 14, and 19-21 have been canceled. Applicant appeals from the rejection of claims 13, 15-18 and 22-36. The appealed claims were reproduced in the Appendix attached to the appeal brief.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The only issue on appeal is whether claims 13, 15-18 and 22-36 are unpatentable under 35 U.S.C. § 103(a) as obvious over Andya in view of Michaelis.

ARGUMENT

Claims 13, 15-18 and 22-36 are not obvious over Andya in view of Michaelis because they recite subject matter not shown or suggested by Andya in view of Michaelis.

Andya in view of Michaelis fails to render obvious any of claims 13, 15-18 and 22-36. Claims 13, 15-18 and 22-36 are directed to a lyophilizate which contains a monoclonal or polyclonal antibody, an amino sugar, at least one amino acid, and a surfactant, where the lyophilizate does not contain polyethylene glycols or additional proteins; a composition containing the lyophilizate and a method for preparing the lyophilizate. The examiner's answer states that formulation 11 in Michaelis "contains an amino sugar (N-methyl-glucosamine), an amino acid (phenylalanine) and a surfactant (maltose) was 1.2 and 1.8 at 8°C and 40°C respectively, where as the %DCP for Formulation 14 containing an amino sugar (N-methyl-glucosamine), glycine (amino acid) and a non-amino acid (Plunaria) was 1.2 and 3.5 at 8°C and 40°C respectively. As such, it appears the Formulation 11 is more stable than the Formulation of 14" (page 7 of the examiner's answer). Applicants respectfully point out that contrary to the examiner's answer, formulation 11 does **not** contain N-methyl-glucosamine (see table 6 of Michaelis). In addition, maltose is a sugar auxiliary agent as defined in column 3, line 62 of Michaelis not a surfactant and Pluronic F68 is a surfactant not a non-amino acid as incorrectly stated in the examiner's answer. Below is a chart which may clarify the compounds contained in formulations 11 and 14 and their classes.

Compound	Compound Class	contained in Formulation 11	contained in Formulation 14
G-CSF	protein	yes	yes
Pluronia F68	surfactant	yes	yes
N-methyl glucosamine Galactosamine	amino-sugar	yes	yes
Glycine Phenylalanine	amino acid	yes	yes
Maltose	sugar (non-amino sugar)	yes	**no**
Storage		% DCP of Formulation 11	% DCP of Formulation 14
+ 8°C		1.2	1.2
+ 40°C		1.8	**3.5**

Applicants agree that formulation 11 is more stable than formulation 14 but the examiner's answer fails to point out that in addition to the protein, surfactant, amino sugar and amino acid, formulation 11 also contains maltose, a non-amino sugar. Formula 11 contains Pluronic F68, galactosamine, maltose and phenylalanine while formulation 14 contains Pluronic F68, N-methyl-glucosamine, and glycine. Thus, Michaelis teaches that a combination containing surfactant, amino sugar, an additional non-amino sugar and an amino acid (formulation 11) produces superior results (for stabilizing a protein) to a combination containing only a surfactant, amino sugar and an amino acid (formulation 14). Applicants contend that this teaches away from the present invention in which the only sugar is an amino sugar. Therefore, combining Michaelis' formulation for stabilizing G-CSF with Andya's antibody preparation would not

result in the present invention even if such formulations could be generalized to apply to any and all pharmaceutical compositions. As discussed in applicant's appeal brief, antibodies and cytokines are in different protein classes and have different structures and therefore different stabilization requirements.

For all of the above noted reasons, it is strongly contended that certain clear differences exist between the present invention as claimed in claims 13, 15-18 and 22-36 and the prior art relied upon by the Examiner. It is further contended that these differences are more than sufficient evidence that the present invention would not have been obvious to a person having ordinary skill in the art at the time the invention was made.

This final rejection being in error, therefore, it is respectfully requested that this honorable Board of Patent Appeals and Interferences reverse the Examiner's decision in this case and indicate the allowability of application claims 13, 15-18 and 22-36.

In the event that this paper is not being timely filed, the applicant respectfully petitions for an appropriate extension of time. Please charge any fee or credit any overpayment pursuant to 37 §C.F.R. 1.16 or §1.17 to Deposit Account No. 02-2135.

Respectfully submitted,

By: 

Monica Chin Kitts
Attorney for Applicant
Registration No. 36,105
ROTHWELL, FIGG, ERNST & MANBECK, p.c.
1425 K Street NW, Suite 800
Washington, DC 20005
Telephone: (202) 783-6040